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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/675,323

09/28/2000

Henry A. Lardy

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08/22/2006

HOLLIS-EDEN PHARMACEUTICALS, INC.

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SAN DIEGO, CA 92121

EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/675,323

Applicant(s)

LARDY ET AL.

Examiner

Elli Peselev

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-39, 56-59, 61, 63-65 and 67-79 is/are pending in the application.
- 4a) Of the above claim(s) 33-39 and 70-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-59, 61, 63-65 and 67-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Upon further consideration the Final Rejection of June 23, 2006 is hereby withdrawn in order to introduce a new ground of rejection.

The provisional rejection of claims 56-59, 61, 63-65 and 67-69 on the ground of nonstatutory obviousness-type double patenting over claim 15 of the copending Application No. 10/319,356 is withdrawn.

Claims 33-39 and 70-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 8, 2003. The disclosure is objected to because of the following informalities: Examples 2-5 on page 80 of the specification are directed to figures. However, the specification does not contain a section titled "Brief Description of Drawings" and no Figures have been presented.

Appropriate correction is required.

Claims 56-59, 61, 63-65, 67-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compound 10 as set forth on page 78 of the specification, does not reasonably provide enablement for the steroid compounds as encompassed by the present claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use and make the invention commensurate in scope with these claims.

A conclusion of lack of enablement means, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would

not have taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

(A) The nature of the invention.

The claims are directed to the treatment of androgen responsive prostate cancer or androgen responsive benign prostatic hyperplasia or amelioration of one or more symptoms thereof by administration of a large number of steroid derivatives.

(B) The predictability or lack thereof in the art.

Chang et al (Proc. Natl. Acad. Sci. USA Vol. 96, Issue 20, 11173-11177, September 28, 1999), submitted by applicants disclose that among 22 derivatives of dehydroepiandrosterone, only 4 steroids were found that have no androgenic activity and could also block the Adiol-induced AR transactivation in prostate cancer PC-3 cells (see, for example, the Abstract). Therefore, Chang et al show that there is great unpredictability in activities of various derivatives of dehydroepiandrosterone.

(C) The presence or absence of working example.

There is a single working example directed to a compound wherein one or R5 or R6 is a carbonate (compound 10 set forth on page 78 of the specification).

(D) The breadth of the claims.

The claims encompass a very large number of species. Note that the claims encompass a large variation in variables R5, R6, R12, R13, R16, R17, R18, R19 and R15. It is noted that the claims have been limited to compounds wherein R5 or R6 is a carbonate. The specification discloses a single species of a compound wherein R5 or R6 is a carbonate and that is a compound 10 as set forth on page 78 of the

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specification. Note that "in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims" (MPEP 2164.03)

The claims encompass an immense number of species.

(E) The quantity of experimentation needed.

Chang et al (Proc. Natl. Acad. Sci. USA Vol. 96, Issue 20, 11173-11177, September 28, 1999) disclose that among 22 derivatives/metabolites of dehydroepiandrosterone, only 4 steroids were found that have no androgenic activity and could block the Adiol-induced AR transactivation in prostate cancer PC-3 cells (see, for example, the Abstract). Because there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Claim 58 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Note that claim 57 is already limited to the structure set forth in claim 58.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(f) he did not himself invent the subject matter sought to be patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56-59, 61, 63-69 are rejected under 35 U.S.C. 102(a and f) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chang et al (Proc. Natl. Acad. Sci. USA Vol. 96, Issue 20, 11173-11177, September 28, 1999).


Chang et al disclose 10, 3-methylcarbonate-androst-5-ene-7, 17-dione having no androgenic activity but being able to block the Adiol-induced AR transactivation in prostate cancer PC-3 cells and being potential therapeutic drug for prostate cancer see, for example the ABSTRACT and DISCUSSION). Based on the disclosure by Chang et al, a person having ordinary skill in the art at the time the claimed invention was made would have envisaged the treatment of prostate cancer with the claimed compound.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev


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